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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Availability of the Draft Supplementary Risk Assessment for the Boston University (BU)

National Emerging Infectious Diseases Laboratories (NEIDL); public hearing

AGENCY: National Institutes of Health.

ACTION: Notice; public hearing announcement.

SUMMARY: The National Institutes of Health has placed in the docket for public review and comment the Draft Supplementary Risk Assessment for the NEIDL, which is intended to respond to the concerns of the local community, courts, the National Research Council, and the general public regarding possible impacts of the laboratory. The purpose of the Draft Supplementary Risk Assessment for the NEIDL is to present the human health consequences of a potential accidental event or malevolent action resulting in the release of a pathogen or loss of biological containment at the NEIDL. Furthermore, this risk assessment compares the potential public health consequences resulting from the potential loss of biocontainment in a range of population density areas that represent urban, suburban, and rural environments. The urban, suburban, and rural sites that were selected for the purposes of the comparative analysis include the Boston University Medical Campus (BUMC) BioSquare Research Park, Boston, where the NEIDL has been constructed; the BU Corporate Education Center in Tyngsborough, Massachusetts; and the BU Sargent Center for Outdoor Education near Peterborough, New Hampshire. The Risk Assessment also examines whether locating the NEIDL in Boston would have a disproportionately high and adverse impacts on low-income and minority populations.

DATES: Comments on the Draft Supplementary Risk Assessment for the NEIDL must be postmarked no later than May 1, 2012. A public hearing to solicit public comment on the document will be held on April 19, 2012, from 6:30-9:30 P.M. at Roxbury Community College, 1234 Columbus Avenue, Boston, MA 02120

ADDRESSES: Written comments should be sent to The National Institutes of Health, Office of Biotechnology Activities, ATTN: NEIDL Risk Assessment, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, 20892. E-mail comments should be sent to NIH_BRP@od.nih.gov. **Please note that comments sent by e-mail must be received by 11:59 p.m. on the last day of the comment period May 1, 2012**

FOR FURTHER INFORMATION CONTACT: National Institutes of Health Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, 20892. Telephone number: 301-496-9838. Electronic mail address: NIH_BRP@od.nih.gov.

SUPPLEMENTARY INFORMATION: The National Institutes of Health awarded a construction grant to Boston University Medical Campus to partly fund the design and construction of one of two National Biocontainment Laboratories. These advanced biomedical research laboratories are essential to the civilian biodefense initiative, providing critically needed Biosafety Levels 2, 3 and 4 research space. The basic and translational research to be conducted in these laboratories over the next 20 years would result in development of new rapid diagnostic assays, vaccines and therapeutics for protection of the American public against intentional misuse or release of harmful biological agents or toxins and naturally emerging and re-emerging infectious diseases.

The NIH completed and published a final Environmental Impact Statement (EIS) and published a Record of Decision as required for major federal actions under the National Environmental Policy Act. Construction of the NEIDL began at the BioSquare II Research Park on Albany Street, Boston, Massachusetts adjacent to the BUMC.

During the preparation of the EIS, the NIH conducted a thorough review of the possible impacts of the NEIDL on the public and the environment. Based on that review, the NIH concluded that the construction and operation of the NEIDL in its current location posed a negligible risk to the surrounding community in which the laboratory was sited.

Several residents and public interest groups filed a federal lawsuit challenging the adequacy of the final EIS prepared for the NEIDL and whether the potential risks of the research would vary depending on the location of the facility in a suburban or rural area. A state lawsuit was also filed challenging the adequacy of a separate environmental review prepared pursuant to a Massachusetts law.

The Draft Supplementary Risk Assessment for the NEIDL addresses the issues raised by the public and the courts regarding pathogen release, facility location, and environmental justice concerns.

Throughout the preparation of the Draft Supplementary Risk Assessment for the NEIDL, NIH has sought the input of the public regarding scenarios and pathogens they wished to see included in the Risk Assessment. In addition, NIH established an independent Blue Ribbon Panel (BRP) to provide scientific and technical advice to the agency in assessing any potential public health risks associated with the operation of the NEIDL and to assess strategies for mitigation. The BRP was convened with 16 members having expertise in relevant fields, including infectious diseases,

public health and epidemiology, risk assessment, environmental justice, risk communications, bioethics, biodefense, biosafety, and infectious disease modeling. The NIH has also sought guidance from the National Research Council (NRC) committee that was critical of the draft of an earlier risk assessment prepared by the NIH.

Availability of Copies and Electronic Access

Given the highly technical nature of the report and in order to assist the reader, a reader's guide will be provided with each copy of the draft supplementary risk assessment

Copies of the Draft Supplementary Risk Assessment Report for the Boston University National Emerging Infectious Diseases Laboratory and the reader's guide document may be obtained at no cost by calling 301-496-9838, or by emailing requests to NIH_BRP@od.nih.gov. The document will also be available electronically at: <http://nihblueribbonpanel-bumc-neidl.od.nih.gov/default.asp>

A copy of the draft supplementary risk assessment and the reader's guide will also be available for review at each of the following locations. Central Branch of the Boston Public Library, 700 Boylston Street, Boston, MA, South End Library, 685 Tremont Street, Boston, MA, Grove Hall Library, 42 Geneva Avenue, and Dudley Library, 65 Warren Street, Boston, MA.

Public Meeting: The National Institutes of Health will hold a public meeting on Thursday, April 19, 2012, from 6:30-9:30 p.m. at Roxbury Community College, 1234 Columbus Avenue, Boston, MA 02120. The purpose of the meeting is to solicit public comments regarding the Draft Supplementary Risk Assessment for the National Emerging Infectious Diseases Laboratories. Comments provided during the meeting, as well as those received during the public comment period will be considered in the Final Supplementary Risk Assessment for the National Emerging Infectious Diseases Laboratories. Individuals wishing to provide oral comments at the meeting

must sign-in prior to the start of the meeting. Sign-in will begin at 5:30 p.m. In order to ensure everyone has the opportunity to speak, comments must be limited to no longer than three minutes. This public meeting is part of the 67-day public comment period initiated with the publication of a Notice of Availability in the Federal Register on February 24, 2012. The 67-day comment period began on February 24, 2012 and will end on May 1, 2012. Comments can also be sent to: The National Institutes of Health, ATTN: NEIDL Risk Assessment, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, or emailed to NIH_BRP@od.nih.gov. For further information concerning this meeting, please contact Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, telephone 301-496-9838, e-mail: BRP_NIH@od.nih.gov.

Dated: February 16, 2012

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